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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,056	09/20/2001	Mark L. Tykocinski	285332-00002-2	6690

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/957,056

Applicant(s)

TYKOCINSKI ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 51-56, 59-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 51-56 and 59-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 23, 51-56 and 59-61 are pending.
Claims 23, 59 and 61 have been amended.
Claims 57 and 58 have been cancelled.
Claims 23, 51-56 and 59-61 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Grounds of Objection

Specification

3. The disclosure continues to be objected to because of the following informality:
on page 13, line 14 it is not clear what the recitation [???] means.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

4. The rejection of claims 23 and 51-61 under 35 U.S.C. 112, second paragraph presented in the Action mailed February 13, 2004 (page 5, section 7), as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 23 and 51-61 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants have amended claim 23 in the submission filed August 9, 2004.

Applicants have also submitted a declaration by Dr. Mark Greene in order to anticipate the instant rejection. Applicants suggest that "[t]he Examiner appears to assert that the claims...do not meet the enablement portion of 112" and [t]he description provides ample information on how to make the fusion proteins, how to transfer the fusion proteins to a cell population and how to use the cells of the present invention in treatment of various diseases", see page 6, paragraph 2 of Remarks. These points of view and the declaration have been carefully considered, but found unpersuasive.

It is clearly established in the Action mailed February 13, 2004 that the written description in this case only sets forth three cells which set forth a defined lipidated protein and defined fusion proteins, which are to be implemented in Applicants' methods, see page 3, section 5, first paragraph. The Examiner further establishes the lack of written description by plainly noting "...claim [23] reads on a multitude of cells comprising numerous proteins and protein derivatives, which are supposed to carry out several functions as set forth by the claim language.", see bridging paragraph of pages 4 and 5. Examiner provides in the Action that Applicants lack presentation of a

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representative of species within the broadly claimed genus and lack of entitlement to such. The rejection was presented as a lack of enablement rejection. Notwithstanding, the claims as written continue to embrace variant species, wherein the first domain is not defined. There is a substantial variation with the genus especially given the non-limiting definitions of fusion protein and lipidated protein. As Applicants' claims are written the cell could include countless numbers of proteins.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

6. Claims 23 and 51-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 23 is vague and indefinite in the recitation "said second domain encoding a protein having a costimulatory, inhibitory or adhesion function". It is art known that protein domains do not encode proteins, but rather nucleic acids encode proteins. Applicants are requested to review the claim and clarify.

Conclusion

7. Claims 23, 51-56 and 59-61 are free of the art.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

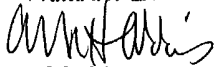
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

14 October 2004